REMARKS

Claims 1, 3, 5, 10, 11, 13 to 15 and 17 to 19 are pending in the above-identified application.

Claims 17 to 19 are withdrawn from consideration. Applicants note the Examiner's statement concerning eligibility of Claims 17 to 19 for rejoining.

Reconsideration of the rejection of this application is respectfully requested in view of the above amendments and the following remarks.

Rejections under 35 USC §112

The Examiner objects to Claim 15 under 35 USC §112 because of the inclusion of "diabetic complications". The objected to term has been removed from Claim 15.

Claims 1, 3, 5, 10, 11 and 13 to 15 are rejected under 35 USC §112, second paragraph.

The Examiner objects to Claim 1 in the definition of "Y" as a "prodrug ester". The definition of "Y" has been amended to delete "prodrug ester" inasmuch as Claim 1 already includes prodrug esters.

Regarding Additional Claim Objections – Pages 9 and 10 of the Official Action

Claim 1 is objected to because the term "alkoxycarbonylaryloxycarbonyl" is repeated twice in the definition of R^3.

The definition of R^3 in Claim 1 has been amended to delete one of the "alkoxycarbonyl-aryloxycarbonyl" groups.

Claim 15 is objected to. The Examiner contends that the terms "dysmetabolic syndrome" and "Syndrome X" are synonyms . . . The term "dysmetabolic syndrome" has been deleted from Claim 15.

The Examiner requests that in Claim 15, the word "such" should be inserted in the penultimate line between the words "of" and "treatment". Claim 15 has been amended accordingly.

Claim 1 has been amended (as suggested by the Examiner) to delete the phrase "or a prodrug ester" in all occurrences in the definition of "Y".

Regarding Claims 17 to 19, which will likely be rejoined upon allowance of the remaining claims, have been amended as suggested by the Examiner. Thus, in Claims 17 to 19 Applicants have replaced the term "combination" with "composition". In addition, in Claim 17 the term "lipid

modulating agent" has been deleted. In Claim 18, Applicants have replaced commas with semi-colons to separate or delineate each class of therapeutic agent. In Claim 18 the term "serotonin (and dopamine) reuptake inhibitor" has been replaced with "serotonin and/or dopamine reuptake inhibitor".

In Claims 17 and 18 the term "and/or" has been replaced by "or".

In view of the foregoing, it is believed that all objections under 35 USC §112 have been overcome.

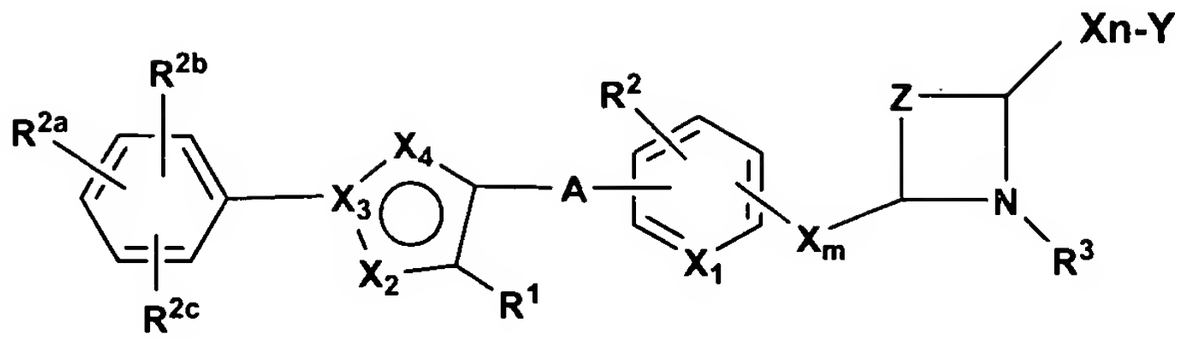
Obviousness Type Double Patenting

Claims 1, 3, 5, 10, 11, 14 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 11 and 12-14 of U.S. Patent No. 7,105,556 (Cheng et al). The Examiner maintains that

> "although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 11 of the patent is drawn to three species, each of which is embraced by instant Claims 1, 3, 5, 10 and 11, wherein 'B' is a bond; R1 is methyl; CH2-CH2-O-; R2 is H; 'D' is a bond; 'Y' is CO2H; R3 is alkoxyaryloxycarbonyl, arylalkylcarbonyl and aryloxyarylalkyl, respectively. Since Claim 11 of the patent depends from Claim 1 thereof, then Claim 1 of the patent is not patentably distinct from instant Claims 1, 3, 5, 10 and 11 either. Since Claim 11 of the patent represents the most preferred species of the generic claim (Claim 1) in that patent, and Claims 12-14 of the patent each depend from that generic claim, then the pharmaceutical composition according to instant Claim 14, and the method according to instant Claim 14 are not patentably distinct from the pharmaceutical composition according to Claim 12 of the patent and the methods according to Claims 13 and 14 of the patent, respectively. The pharmaceutical composition and methods as specified in the claims of the patent are practiced with species from Claim 11 thereof, and as such, the composition and method specified in the claims of the patent are not patentably distinct from the corresponding claims in the instant application."

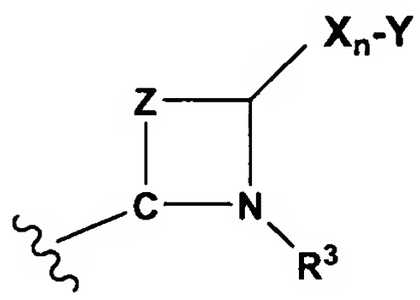
Applicants submit that the invention as claimed herein is patentable over the claims of U.S. Patent No. 7,105,556 to Cheng et al.

Cheng et al. discloses and claims compounds of the structure

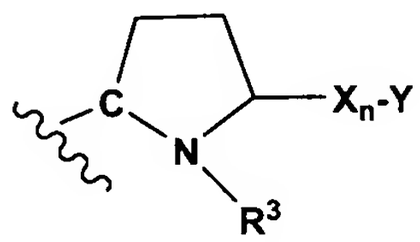


wherein Z is $(CH_2)_x^4$ wherein x^4 can be 1 to 5 with the elected x^4 being 2.

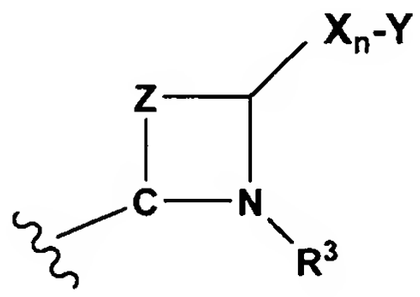
Thus, the ring



as defined in Claim 1 is



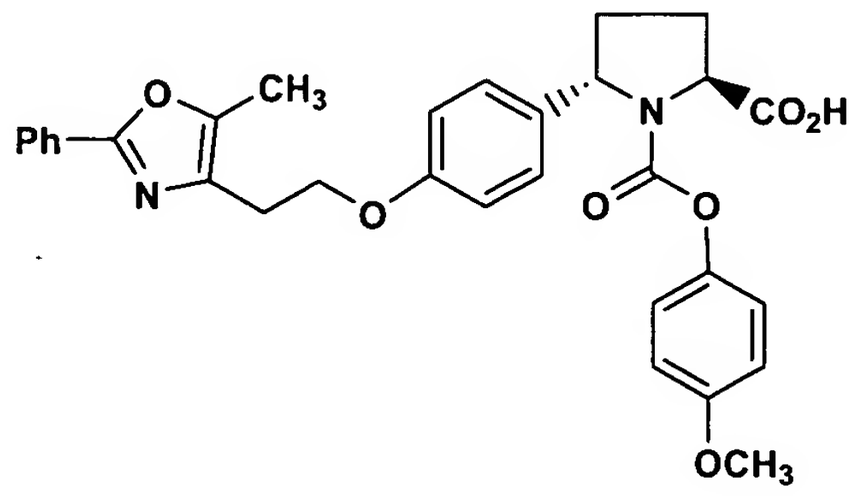
Please note that the ring is linked to the rest of the molecule via an ortho carbon (that is ortho to the N atom). All of the compounds in Cheng et al. include the ring

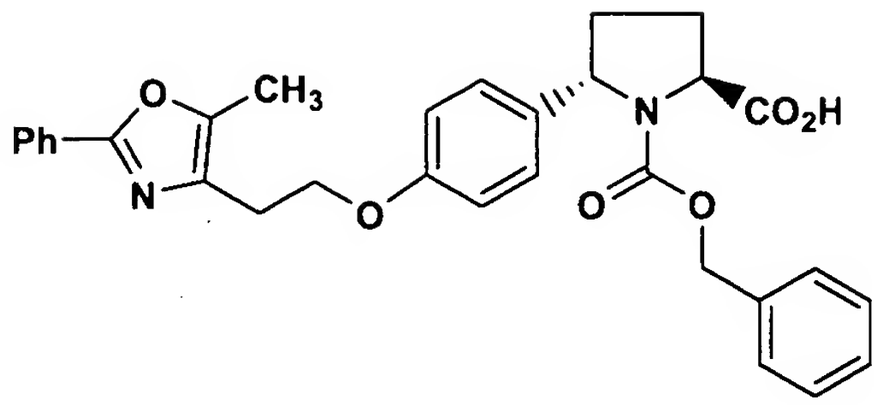


which is linked to the remainder of the molecule via an ortho carbon (ortho to the N atom).

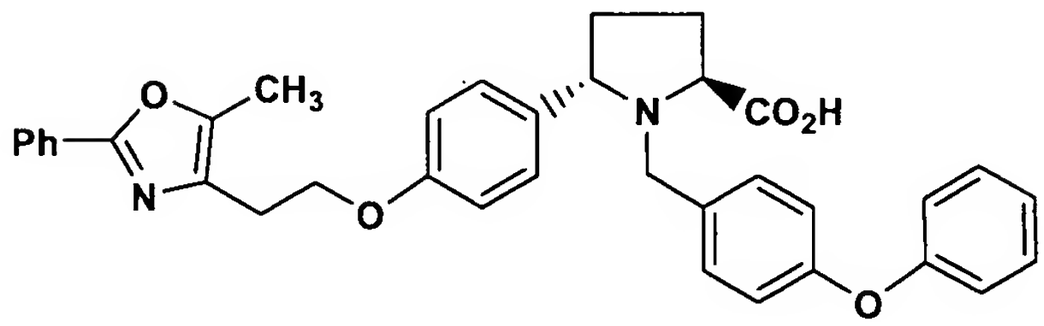
Set out below are the 3 compounds defined in Claim 11 of Cheng et al.

Claim 11. The compound as defined in claim 1 having the structure

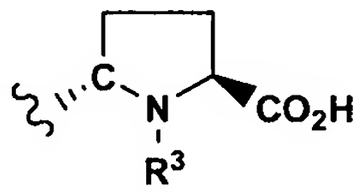




or

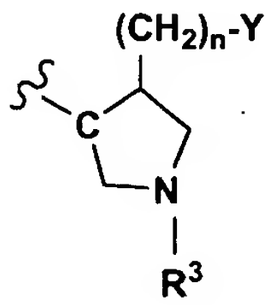


Please note that the ring



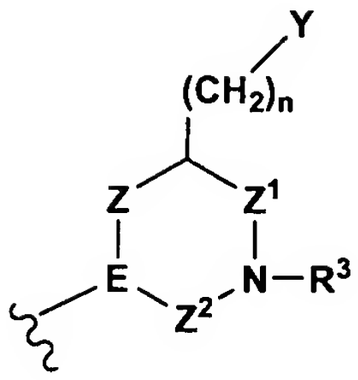
in each of the Cheng et al Claim 11 compounds is linked to the remainder of the molecule by the carbon ortho to the N atom.

The compounds as claimed herein include the ring moiety



Please note that the above ring is linked to the remainder of the molecule via a meta carbon (and not a carbon ortho to the N atom as in Cheng et al.). Thus, the compounds as claimed herein include the N containing ring which is always linked to the rest of the molecule via a carbon meta to the N atom and which is <u>not</u> ortho to the N atom and therefore are not encompassed by Claim 11 or any of the other claims of Cheng et al.

The Cheng et al. claims as filed include the ring moiety



wherein

Z^1 is $(CH_2)_q$ or C=O where q is 0, 1 or 2;

Z^2 is $(CH_2)_p$ or C=O where p is 1 or 2;

Z can be a single bond; and

E can be CH.

Please note that in all cases of the above ring systems, the ring is never attached to the remainder of the molecule via an ortho carbon since Z^2 must include a C. One skilled in the art reading the claims of Cheng et al. would have no motivation to change the position of the linking molecular portion to other than the ortho position on the ring.

Thus, in view of the above differences, which differences are unobvious, it is submitted that Applicants' compounds as claimed are patentable over the claims of Cheng et al.

In order to expedite prosecution of the subject application, Applicants submit herewith a terminal disclaimer in compliance with 37 CFR §1.321 (e) wherein the present application and the Cheng et al. patent are shown to be commonly owned and wherein Applicants disclaim the term of any patent issuing from the subject application which extends beyond the term of the Cheng et al. patent.

In view of the foregoing, it is believed that the obviousness double patenting rejection over Cheng et al. has been overcome.

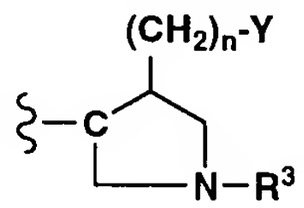
Claims 1, 3, 5, 10, 11, 14 and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 13 and 15 of co-pending Application No. 11/406,799 (pursuant to the Preliminary Amendment filed in that application April 19, 2006). The Examiner maintains that

> "although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the co-pending application, although broadly generic, when interpreted in light of the accompanying disclosure, renders obvious the compounds of the present invention. Specifically, if the disclosure of the co-pending application is consulted as a dictionary to provide a more specific

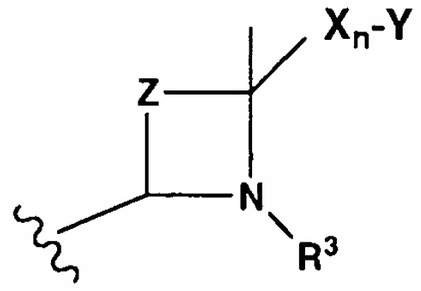
understanding of what compounds applicants consider the invention in that application, at page 5 thereof, one finds that at least two of the preferred compounds of the invention are squarely within the scope of the instant claims. The fourth and fifth molecular structure representations on page 5 of the specification of the co-pending application are compounds according to instant claims 1, 3, 5, 10 and 11 wherein "B" is a bond; R^1 is methyl; $-CH_2-CH_2-O$; R^2 is H; "D" is a bond; "Y" is CO_2H; R^3 is arylalkylcarbonyl and aryloxyarylalkyl, respectively. Thus, the pharmaceutical composition according to claim 13 of the co-pending application and the method for treating diabetes according to claim 15 of the co-pending application render obvious the corresponding composition and method of instant claims 14 and 15, respectively."

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is submitted that the same arguments to show patentability of the compounds as claimed herein over the invention claimed in co-pending application No. 11/406,799 as set out with respect to the Cheng et al. patent apply here as well. In the subject application the ring



is linked to the remainder of the molecular meta via a carbon (meta to the N atom) and not a carbon ortho to the N atom as in the compounds shown on page 5, 4th and 5th structures in co-pending application No. 11/406,799. There would be no motivation for one skilled in the art reading the specification and claims of co-pending application No. 11/406,799 to change the structure of the compounds covered in the claims so that the ring



is linked other than through the carbon ortho to the N atom.

In view of the above differences, which differences are unobvious, it is submitted that Applicants' compounds as claimed are patentable over the claims of co-pending Application No. 11/406,799.

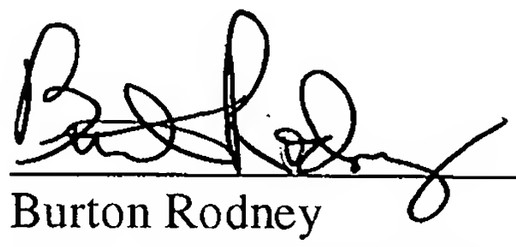
In order to expedite prosecution of the subject application, Applicants submit herewith a terminal disclaimer in compliance with 37 CFR §1.321(e) wherein the present application and the

Application No. 11/406,799 are shown to be commonly owned and wherein Applicants disclaim the term of any patent issuing from the subject application which extends beyond the term of a patent which issues from application No. 11/406,799.

In view of the foregoing, it is believed that the obviousness double patenting rejection over Application No. 11/406,799 has been overcome.

In conclusion, it is submitted that Claims 1, 3, 5, 10, 11, 13, 14 and 15 as present and amended are in compliance with 35 U.S.C. §112 and overcome the cited Cheng et al and Application No. 11/406,799 and therefore are in condition for allowance.

Respectfully submitted,



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Date: March 7, 2007